REMARKS

In the specification, paragraph [0020] has been amended to correct a typographical error.

Claims 3, 5-15, 17-18, and 22-37 remain in this application. Claims 27-37 have been added. All of the new claims are dependent claims and therefore narrow the scope of claims already in this case. Claims 27-31 are added to more particularly claim the positioner geometry. Claims 32-33 are added to more particularly claim the alternative embodiments encompassed by claim 17 as pointed out by Examiner. Claim 34 is added to more particularly claim the lateral spacing aspects of the positioner. Claims 35-37 are added to more particularly claim the method for using the positioner to radially space the femoral hip implant. Claims 27-33 find support in the specification in paragraphs [0022] through [0029] and in Figures 1-3. Claims 34-37 find support in the specification in paragraph [0030] and in Figures 1-3.

The examiner has indicated that claims 11-14 are allowed and that claims 25-26 contain allowable subject matter.

TECHNICAL REJECTIONS

Claims 3, 5-10, 17, 18, and 25-26 are rejected under 35 U.S.C. 101.

Examiner states that in claims 3, 17 and 18 the femoral canal is positively claimed in the body of the claim. Claims 3, 17, and 18 have been amended to remove most references to the femoral canal. The remaining references reference the femoral canal inferentially where it is

used to provide an environmental reference for explaining the structure of the claimed device and the environment in which it is used.

Similarly, claim 3 adds the "head" as an element. The pelvic portion of the hip joint is inferentially referenced in describing the environment in which the head operates. Support for this element is found in paragraphs [0020] and [0022] head and pelvis. These amendments overcome the rejection and claims 3, 5-10, 17, 18, and 25-26 are now allowable under 35 U.S.C. 101.

Claim 17 is rejected under 35 U.S.C 112.

Examiner contends that the specification does not enable the claim clause "a third member projecting from one of the first and second members" because the specification only shows a third member projecting from the first member. Applicant respectfully disagrees. Claim 17 includes a "a third member projecting from one of the first and second members to engage the femoral hip implant to maintain the femoral hip implant at a predetermined radial position within the femoral canal". The specification describes radial positioning in paragraphs [0027] and [0028]. In paragraph [0027], "the radial spacing of the boss 70 and one or more of the legs 62, 64, 66 maintains a predetermined spacing between the femoral component 36 and canal 14 wall 20." In paragraph [0028], "the tabs 68 may project a sufficient predetermined distance to substantially fill the space between the femoral component 36 and the canal 14 wall 20 and act to radially space the femoral component 36 from the canal 14 wall 20. The tabs 68 and boss 70 may be separately used or used in combination as shown." Both the boss 70 and the tabs 68

satisfy the requirement of claim 17 of a "third member" for radial spacing; the boss extends from the first member and a tab extends from the second member. Thus, Applicant believes that the use specification is fully enabling of the breadth of claim 17 and Applicant respectfully requests withdrawal of this rejection.

Claims 32 and 33 have been added to specifically claim the alternate embodiments discussed relative to claim 17 above. These claims depend from claim 17 are allowable for the same reasons as claim 17.

Claim 3, 5-10, and 18 are rejected under 35 U.S.C. 112.

Examiner points out that it is unclear which state (implanted or unimplanted) of the device is being claimed. Claims 3 and 18 has been amended to clarify that the device is claimed in the unimplanted state. Applicant believes that claims 3, 5-10, and 18 are now allowable under 35 U.S.C. 112.

The only rejections of claims 3 and 17 were under 35 U.S.C. 101 and 112. The only rejection of claims 5-10 was the rejection under 35 U.S.C. 101 directed to claim 3. Claims 3 and 17 have been amended to overcome the rejections. Claims 5-7 and 9 have been amended for grammatical consistency and clarity. Applicant asserts that claims 3, 5-10, and 17 are now in condition for allowance.

ART REJECTIONS

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Mathys, Sr. et al.

Examiner points to Mathys' screw 9 as a positioner and claims that the head is means for preventing the hip implant from rising from the canal while permitting subsidence of the hip implant down into the canal and that the screw is means for anchoring the means for preventing relative to the femoral canal.

Mathys' screw 9 is placed obliquely through his implant and into the femur. If Mathys' screw 9 prevents his implant from rising from the femoral canal, then it equally prevents his implant from subsiding distally into the cement mantel due to the transverse placement of the screw. Note that the portion of the implant 7 above the screw 9 is suspended on the screw 9 preventing the implant from subsiding. Mathys specifically states the purpose and effect of screw 9 at column 3 line 67 to column 4 line 2; "**displacements between the screw 9 and the bone as well as the prosthesis collar are prevented**". Thus, Mathys specifically states that his implant cannot rise or subside and teaches away from Applicant's positioner for allowing subsidence. Thus, Mathys' device does not "limit upward axial motion of the femoral hip implant while permitting downward axial motion" and claim 15 is allowable over Mathys.

Claims 27-31 have been added and depend from claim 15. These claims are allowable for the same reasons as claim 15.

Claim 27 is further allowable over Mathys since Mathys fails to teach "the second member [being] simultaneously positionable along the exterior surface of the stem between the stem and the canal wall." Mathys' screw is a linear device place transversely through the implant and bone. It cannot simultaneously overlie the implant and lie along the exterior surface of the stem

between the stem and canal wall. Furthermore, Mathys teaches away from cement and teaches an implant that fills the canal such that there would be now room for a second member between the stem and canal wall.

Claim 28 is further allowable over Mathys since Mathys fails to teach "the second member extending around the exterior of the implant.

Claim 29 is further allowable over Mathys since Mathys fails to teach "a first leg that curves downwardly from the top approximately 90 degrees, the positioner further including a second leg extending from the top and curving downwardly approximately 90 degrees, and a third leg extending from the top and curving downwardly approximately 90 degrees such that the first, second, and third legs are positionable along first, second, and third sides of the femoral hip implant."

Claim 30 is further allowable over Mathys since Mathys fails to teach "a boss projecting downwardly from the first member, the legs each curving downwardly approximately parallel to the boss and surrounding the boss."

Claim 31 is further allowable over Mathys since Mathys fails to teach "each leg further compris[ing] a tab extending inwardly toward the boss."

Claims 1 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpenter et al.

Claim 1 has been canceled.

Relative to claim 24, Carpenter fails to teach that "downward subsidence of the femoral hip implant is unimpeded by the positioner ." Carpenter instead teaches a stem and distal spacer combination that fixes the distal end of the stem and **prevents** the stem from subsiding. Carpenter's spacer 40 is engaged with his stem by fitting post 46 into bore 52 prior to insertion of the assembly into the uncured cement mantel. When the cement cures, the spacer is chemically bonded to the cement. See 40:19-27. Thus, the implant is blocked by the chemically bonded spacer from subsiding. Thus, claim 24 is allowable over carpenter.

Furthermore, Carpenter fails to teach "a retention member positioned above a portion of the implant such that upward motion of the femoral hip implant beyond a predetermined position is limited by abutment of the portion against the retention member". Carpenter's spacer does not abut the stem if the stem rises. On the contrary, Carpenter's spacer is made to engage the stem entirely below the stem and is **incapable of abutting the stem upon the stem arising. The spacer would separate from the stem upon the stem rising.**

Carpenter is the antithesis of Applicant's invention and a complete teaching away from it in that Carpenters device is positioned, and chemically bonded to the cured mantel, such that **it prevents subsidence, while being incapable of abutting the stem to prevent rising.** Thus, claim 24 is allowable over Carpenter.

Claims 35-37 depend from claim 24 and are allowable for the same reasons as claim 24.

Claims 15 and 22 are rejected under 34 U.S.C. 102(b) as being anticipated by Link.

Examiner states that Link teaches a positioner with means (element 10) for preventing the femoral hip implant from rising out of the canal while permitting subsidence including element 10.

Applicant respectfully disagrees. Link teaches a cementless stem with a collar 10 including an anchoring 15, 16 to the greater trochanter "such that both the greater trochanter 2, via the anchoring 15, 16, and also the medial area of the bone 3, via direct contact with the adjacent part of the stem 6, participate in the bone taking up the forces acting medially on the prosthesis". Link's collar is a "support collar" that transmits vertical forces to the bone. See 1:15-27, 2:10-20. Link's collar is secured to the stem so that the stem cannot move relative to the stem. See grooves and ribs 17 and screw 18. Notwithstanding the grooves, ribs, and screws, Links collar would also prevent subsidence due to impingement of the neck 8 on the collar 10.

Link teaches away from allowing subsidence since the focus of Link's teaching (and invention) is the provision of a collar that **prevents subsidence. The collar 10 is fixed to the stem and to the bone to prevent movement of the stem in either direction.**

Relative to claim 15, Link fails to teach "limit[ing] upward axial motion of the femoral hip implant while permitting downward axial motion" and thus, claim 15 is allowable over Link.

Claims 27-31 have been added and depend from claim 15. These claims are allowable for the same reasons as claim 15.

Claim 27 is further allowable over Link since Link fails to teach "the second member [being] simultaneously positionable along the exterior surface of the stem between the stem and the canal wall." Furthermore, Link teaches away from cement and teaches an implant the fills the canal such that there would be now room for a second member between the stem and canal wall.

Claim 28 is further allowable over Link since Link fails to teach "the second member extending around the exterior of the implant to engage a cement mantel surrounding the femoral stem."

Claim 29 is further allowable over Link since Link fails to teach "a first leg that curves downwardly from the top approximately 90 degrees, the positioner further including a second leg extending from the top and curving downwardly approximately 90 degrees, and a third leg extending from the top and curving downwardly approximately 90 degrees such that the first, second, and third legs are positionable along first, second, and third sides of the femoral hip implant."

Claim 30 is further allowable over Link since Link fails to teach "a boss projecting downwardly from the first member, the legs each curving downwardly approximately parallel to the boss and surrounding the boss."

Claim 31 is further allowable over Link since Link fails to teach "each leg further compris[ing] a tab extending inwardly toward the boss."

Relative to claim 22, Link fails to teach "an "L"-shaped body having a first leg positionable over a portion of the femoral hip implant relative to the and a second leg simultaneously positionable within the canal adjacent the canal wall between the femoral hip implant and the canal wall to maintain a predetermined spacing between the femoral hip implant and the canal wall while permitting downward motion of the implant into the canal." On the contrary, elements 13 extend straight back from the collar 10 and cannot be positioned in the canal while the collar 10 is over the implant. Furthermore, Link teaches a canal filling implant such that

there is no room for an element between the implant and the canal wall. Finally, as previously pointed out, Link specifically and positively prevents subsidence.

Claims 23 and 34 depend from claim 22 and are allowable for the same reasons as claim 22.

Claims 15, 18, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Spotorno et al.

Examiner states that Spotorno's members 8, 7 extend over the implant to limit upward movement and permit downward movement.

Applicant respectfully disagrees. Spotorno teaches a proximal centering apparatus that includes a centering wedge 6 that is placed in the proximal femoral canal to space the hip stem from the medial side of the canal. The wedge is temporarily connected by webs 7 to a clamp 8 (FIG. 1) or a cap 12 (FIG. 3). The clamp or cap is provided to connect the wedge 6 to the neck or cone of the hip implant during implantation to position the wedge 6 at a predetermined position relative to the neck or cone. Once the implant is secured in the cement, the webs 7 and clamp 8 or cap 12 are removed to permit completion of the operation.

Spotorno's device is intended to provide accurate positioning of the centering wedge during surgery. See Spotorno paragraphs [0002] through [0004]. He shows no appreciation of, or even awareness of, the need to allow subsidence of a stem postoperatively or the need to prevent a stem from rising from the femoral canal.

Relative to claim 15, Spotorno fails to teach "a first member positionable proximally over a portion of the femoral hip implant". Elements 7 and 8 are positioned on the sides of the neck

and under the medial side of the implant. Furthermore, Spotorno fails to teach "a second member extending at an angle from the first member, the second member being securable relative to the femoral canal such that the positioner limits upward axial motion of the femoral hip implant while permitting downward axial motion of the femoral hip implant postoperatively during articulation of the joint." Elements 7 and 8 do nothing to block the rise of the implant from the femoral canal. Note that during axial upward motion the implant is free to disengage from and move away from elements 7, 8 and 11. Furthermore, all of the elements 7, 8, and 11 as well as the wedge 6 block subsidence of the implant downwardly. Thus, Spotorno device is the antithesis of Applicants claimed invention in that it allows upward motion while preventing subsidence. Thus, claim 15 is allowable over Spotorno.

Note that most of Spotorno's device, including the clamp or cap and webs are totally removed before the device is put into service. Only the wedge 6 remains during articulation of the joint and the wedge 6 does not overlie the implant or otherwise provide a way to limit upward axial motion and it blocks subsidence.

Claims 17-31 depend from claim 15 and are allowable for the same reasons as claim 15.

Relative to claim 18, Spotorno fails to teach "a retention member engageable with a portion of the femoral hip implant such that it blocks upward motion of the implant out of the canal while permitting downward motion of the implant into the canal during articulation of the joint. Thus, claim 18 is allowable for the same reasons as claim 15.

Relative to claim 22, Spotorno fails to teach "an "L"-shaped body having a first leg positionable over a portion of the femoral hip implant relative to the ". Spotorno has no leg "over a portion of the femoral implant relative to the ". Furthermore, Spotorno fails to teach "a

second leg simultaneously positionable within the canal adjacent the canal wall between the femoral hip implant and the canal wall to maintain a predetermined spacing between the femoral hip implant and the canal wall while permitting downward motion of the implant into the canal." As pointed out relative to claim 15, Spotorno permits upward motion while preventing downward motion. Thus, claim 22 is allowable over Spotorno.

Claim 23 depends from claim 22 and is allowable for the same reasons as claim 22. Claim 23 is further allowable over Spotorno since Spotorno fails to teach "the first leg being positionable over the shoulder of the femoral hip implant." Spotorno's device engages the anterior, posterior, and medial sides of the implant to prevent subsidence while doing nothing to prevent upward motion.

New claim 34 depends from claim 22 and is allowable for the same reasons as claim 22. Claim 34 is further allowable over Spotorno since Spotorno fails to teach "the second leg engageable with the lateral aspect of the femoral canal to maintain a predetermined spacing between the stem and the lateral aspect of the femoral canal." Spotorno's wedge engages the medial aspect of the femoral canal.

Relative to claim 24, Spotorno fails to teach "inserting an implant positioner adjacent to the femoral hip implant with . . . a retention member positioned above a portion of the implant such that upward motion of the femoral hip implant beyond a predetermined position is limited by abutment of the portion against the retention member while downward subsidence of the femoral hip implant is unimpeded by the positioner during articulation of the hip joint in normal use by a patient". Spotorno has no retention member above a portion of the implant. Spotorno

further allows upward motion while preventing subsidence which is exactly opposite the claimed invention.

Claims 35-37 depend from claim 24 and are allowable for the same reasons as claim 24.

Claim 35 is further allowable over Spotorno since Spotorno fails to teach "a boss extending downwardly from the retention member and inserting the positioner further comprises engaging the boss with the femoral hip implant to space the femoral hip implant a predetermined distance from the anchor member." In Spotorno, there is no boss and the anchor member (wedge 6) is not spaced from the implant at all but is in intimate contact with the anchor.

Claim 36 is further allowable over Spotorno since Spotorno fails to teach "a tab extending inwardly toward the femoral hip implant from the anchor member and inserting the positioner further comprises engaging the tab with the femoral hip implant to space the femoral hip implant a predetermined distance from the anchor member." In Spotorno, there is no tab and the anchor member is not spaced from the implant at all but is in intimate contact with the anchor.

Claim 37 is further allowable over Spotorno since Spotorno fails to teach "first, second, and third legs extending downwardly from the retention member and inserting the positioner further comprises placing the first, second, and third legs in the cement adjacent anterior, lateral, and posterior sides of the femoral hip implant." Spotorno only has the wedge 6 that is placed in cement.

Applicant believes that the claims remaining in this case are in condition for allowance and respectfully requests that a timely Notice of Allowance be issued in this case. Applicant has tried to be as clear as possible in any amendments and remarks made in this paper. Applicant invites

Examiner to call the number listed below to discuss any portion of this paper that may be unclear or where minor corrections may put the case in condition for allowance to facilitate a timely allowance of this case.

Respectfully submitted,

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